

WHAT IS CLAIMED IS:

1. A compound that is a crystalline Form III of losartan potassium.
2. The compound of claim 1 having X-ray powder diffraction pattern substantially as shown in Figure 1.
3. The compound of claim 1 having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.15 ± 0.09 , 7.58 ± 0.09 , 8.04 ± 0.09 , 12.38 ± 0.09 , 13.23 ± 0.09 , 13.91 ± 0.09 , 15.27 ± 0.09 , 16.04 ± 0.09 , 17.19 ± 0.09 , 17.79 ± 0.09 , 18.48 ± 0.09 , 18.76 ± 0.09 , 19.29 ± 0.09 , 19.57 ± 0.09 , 20.73 ± 0.09 , 21.58 ± 0.09 , 24.19 ± 0.09 , 24.90 ± 0.09 , 25.67 ± 0.09 , 26.09 ± 0.09 , 27.77 ± 0.09 , 28.91 ± 0.09 , 29.47 ± 0.09 and 30.61 ± 0.09 degrees.
4. The compound of claim 1 having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.154, 7.583, 8.042, 12.385, 13.233, 13.911, 15.267, 16.043, 17.194, 17.794, 18.483, 18.76, 19.293, 19.571, 20.728, 21.576, 24.192, 24.904, 25.695, 26.088, 27.773, 28.908, 29.474 and 30.614 degrees.
5. The compound of claim 1 having a Differential Scanning Colorimetry (DSC) thermogram exhibiting a significant endo peak at about 264°C.
6. The compound of claim 5 having a characteristic DSC thermogram substantially as shown in Figure 2.
7. The compound of claim 1 having a characteristic infrared spectrum exhibiting significant bands at about 1580 cm^{-1} , 1460 cm^{-1} , 1422 cm^{-1} , 1358 cm^{-1} , 1257 cm^{-1} , 1112 cm^{-1} , 1075 cm^{-1} , 999 cm^{-1} , 754 cm^{-1} , and 668 cm^{-1} .

8. The compound of claim 7 having the infrared spectrum substantially as depicted in Figure 3.

1. 9. The compound of claim 1 having a melting range of about 254 to about 260°C.

10. A composition comprising losartan potassium as a solid, wherein at least 80% by weight of said solid losartan potassium is its crystalline Form III.

11. The composition of claim 10, wherein at least 90% by weight of said solid losartan potassium is its crystalline Form III.

12. The composition of claim 10, wherein at least 95% by weight of said solid losartan potassium is its crystalline Form III.

13. The composition of claim 10, wherein at least 99% by weight of said solid losartan potassium is its crystalline Form III.

14. The composition of claim 10, wherein said solid losartan potassium is substantially free of crystalline Forms I and II of losartan potassium.

15. The composition of claim 10, wherein at least 1% of said solid losartan potassium is not its crystalline Form III.

16. The composition of claim 10, wherein at least 5% of said solid Losartan Potassium is not its crystalline Form III.

17. A pharmaceutical or veterinary composition comprising the compound of claim 1 and a pharmaceutically or veterinarily acceptable carrier or diluent.

18. The composition of claim 17, further comprising one or more pharmaceutically acceptable excipients.

19. The composition of claim 18, wherein said pharmaceutical composition is a solid dosage form for oral administration.

20. The composition of claim 19, wherein said solid dosage form is a tablet.

21. The pharmaceutical or veterinary composition of claim 17, wherein the compound of claim 1 is present in the amount of from about 0.01 % to about 99.99 % by weight.

22. The pharmaceutical or veterinary composition of claim 21, wherein the compound of claim 1 is present in the amount of from about 1 % to about 95 % by weight.

23. The pharmaceutical or veterinary composition of claim 22, wherein the compound of claim 1 is present in the amount of from about 2 % to about 20 % by weight.

24. The pharmaceutical or veterinary composition of claim 23, wherein the compound of claim 1 is present in the amount of from about 1 % to about 10 % by weight.

25. The pharmaceutical or veterinary composition of claim 17, wherein the carrier or diluent is a solid or a liquid.

26. The pharmaceutical or veterinary composition of claim 17, wherein the carrier or diluent is selected from the group consisting of a derivatized cellulosic material, starch, polyhydroxylated alcohol, and mixtures thereof.

27. The pharmaceutical or veterinary composition of claim 17, further comprising an ingredient selected from the group consisting of lubricants, disintegrants, coloring agents, anti-hygroscopic agents, binders, pH adjusting agents, flavoring agents, or aromatic agents.

28. The pharmaceutical or veterinary composition of claim 17, which is in the form of a topical or systemic formulation.

29. The pharmaceutical or veterinary composition of claim 17, which is in the form of an oral, injectable, transdermal, implantable, inhalable, transmucosal, or dermal formulation.

30. The pharmaceutical or veterinary composition of claim 17, which is in the form of powder, tablets, dragees, capsules, oil, cream, solution, emulsion, or suspension.

31. A process for preparing crystalline Form III of losartan potassium, said process comprising:

- a) providing a potassium salt of losartan as a solution in a first alcoholic solvent;

b) cooling said solution thereby causing separation of a solid mass;

c) isolating said solid mass which the Form III crystalline Form III of losartan potassium.

32. The process of claim 31, further comprising removing at least a portion of said first alcoholic solvent before said cooling step.

33. The process of claim 31, further comprising reacting trityl losartan with potassium hydroxide to obtain the starting potassium salt of losartan.

34. The process of claim 33, wherein said reacting step includes contacting said trityl losartan with the potassium hydroxide in a second alcoholic solvent and heating said second alcoholic solvent to reflux until the reaction is substantially complete.

35. The process of claim 34, further comprising removing at least a portion of said second alcoholic solvent, and combining the reaction mixture with water and a water-immiscible solvent to form a two-phase liquid system.

36. The process of claim 35, further comprising separating said layers of said two-phase liquid system, isolating the aqueous layer, and reducing the amount of water present therein.

37. The process of claim 36, further comprising combining the reduced aqueous layer with a second water-immiscible solvent capable of forming an azeotropic mixture with water, and heating said second water-immiscible solvent to reflux with removal of the distillate thereby reducing the amount of the water.

38. The process of claim 37, further comprising adding a lower alkanol thereby providing said starting solution of the potassium salt of losartan in the first alcoholic solvent.

39. The process of claim 38, wherein substantially all of said first alcoholic solvent is the lower alkanol.

40. The process of claim 39, wherein the lower alkanol is a C₁-C₄ straight or branched chain alkanol.

41. The process of claim 40, wherein said lower alkanol is selected from the group consisting of methanol, ethanol, isopropanol, n-butanol, iso-butanol, tert-butanol, and mixtures thereof.

42. The process of claim 40, wherein said lower alkanol is methanol.

43. The process of claim 31, wherein said first alcoholic solvent is a mixture of lower alkanol and at least one aromatic solvent.

44. The process of claim 33, wherein the trityl losartan and the potassium hydroxide are reacted at the molar ratio ranging from about 0.5:1.5 to about 1.5:0.5.

45. The process of claim 31, wherein said cooling step is carried out at the temperature ranging from about 0°C to about 50°C.

46. The process of claim 31, wherein said isolating step is filtration of said solid mass.

47. The process of claim 34, wherein said second alcoholic solvent is different from said first alcoholic solvent.

48. The process of claim 34, wherein said second alcoholic solvent is methanol, ethanol, isopropanol, n-butanol, iso-butanol, tert-butanol, or a mixture thereof.

49. The process of claim 37, wherein said second water-immiscible solvent is different than said first water-immiscible solvent.

50. The process of claim 37, wherein said second water-immiscible solvent and said first water-immiscible solvent, which may be same or different, are selected from the group consisting of benzene, xylene, toluene, ethyl benzene, or mixtures thereof.

51. The process of claim 45, further comprising drying said separated mass at the temperature of from about 30 to about 100°C.

52. The process of claim 43, wherein said at least one aromatic solvent is selected from the group consisting of benzene, xylene, toluene, ethyl benzene, or mixtures thereof.

53. The process of claim 52, wherein said providing step includes dissolving a crystalline Form I of potassium losartan in said at least one aromatic solvent and adding said lower alkanol thereto.

54. The process of claim 53, wherein said lower alkanol is selected from the group consisting of methanol, ethanol, isopropanol, n-butanol, iso-butanol, tert-butanol, and mixtures thereof.

55. The process of claim 53, wherein said lower alkanol is methanol.

56. The process of claim 53, further comprising removing at least a portion of said first alcoholic solvent.

57. The process of claim 56, further comprising cooling the reaction mass to cause separation of a solid mass.

58. The process of claim 57, further comprising isolating the separated mass which is the crystalline Form III of potassium losartan.

59. The process of claim 43, wherein the aromatic solvent comprises toluene.

60. The process of claim 53, wherein the crystalline Form I losartan potassium is combined with said aromatic solvent at a temperature of from about 50°C to about 80°C.